Aurora Health Care

Memo

Research Subject Protection Program

Date: June 5, 2013

To: Investigators and Research Staff

From: Research Subject Protection Program (RSPP) Office

Re: Study Expiration Dates on Informed Consent Documents

In light of the National Cancer Institute (NCI) Central IRB recently announcing that expiration dates will no longer be included on informed consent documents, we in the Aurora RSPP office reviewed our current practice. We have decided to remove the study expiration dates from our informed consent templates as well.

In addition to the NCI example, several considerations led us to this decision:

- Inclusion of an expiration date is not required by federal regulations, relevant OHRP and FDA guidance, or AAHRPP accreditation standards.
- Removal of the expiration date will reduce administrative burden, because no update to the consent document will be needed at continuing review.
- The expiration date provides no information that is relevant to subjects, and could lead to confusion that their consent expires.
- Using an informed consent document with a past expiration date is a violation, even if everything else in the document is current. Removing the expiration date eliminates this potential violation.

Please feel free to share this information with others, as needed.